Amendment to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1. (Currently amended) A pharmaceutical composition comprising solid microparticles comprising:

(a) a matrix of:

(i) a lipid selected from the group consisting of phosphoglycerides; phosphatidylcholines; dipalmitoyl phosphatidylcholine (DPPC); dioleylphosphatidyl ethanolamine (DOPE); dioleyloxypropyltriethylammonium (DOTMA); dioleoylphosphatidylcholine; cholesterol; cholesterol ester; diacylglycerol; diacylglycerolsuccinate; diphosphatidyl glycerol (DPPG); hexanedecanol; fatty alcohols; polyethylene glycol (PEG); polyoxyethylene-9-lauryl ether; a surface active fatty acid; palmitic acid; oleic acid; fatty acids; fatty acid amides; sorbitan trioleate (Span 85) glycocholate; surfactin; a poloxomer; a sorbitan fatty acid ester; sorbitan trioleate; lecithin; lysolecithin; phosphatidylserine; phosphatidylinositol; sphingomyelin; phosphatidylethanolamine (cephalin); cardiolipin; phosphatidic acid; cerebrosides; dicetylphosphate; dipalmitoylphosphatidylglycerol; stearylamine; dodecylamine; hexadecyl-amine; acetyl palmitate; glycerol ricinoleate; hexadecyl sterate; isopropyl myristate; tyloxapol; poly(ethylene glycol)5000-phosphatidylethanolamine; and phospholipids;

(ii) a sugar selected from the group consisting of galactose, lactose, glucose, maltose, starches, cellulose and its derivatives, methyl cellulose, carboxymethyl cellulose, fructose, dextran and its derivatives, raffinose, mannitol, xylose, dextrins, glycosaminoglycans, sialic acid, chitosan, hyaluronic acid, and chondroitin sulfate; and

(iii) a protein selected from the group consisting of an albumin, a gelatin, whole cell extracts, antibodies, enzymes, commercially available proteins, proteins purified from natural sources, recombinant proteins, and chemically synthesized proteins; and

(b) at least one pharmaceutical agent; and

~~comprising an agent and a matrix comprising lipid, protein, and sugar,~~ wherein the microparticles are not liposomes;

wherein the pharmaceutical agent is encapsulated in the matrix;

wherein the microparticles are less than 50 micrometers in diameter;

wherein the lipid comprises 20-60% of the matrix by weight;

wherein the protein comprises 10-30% of the matrix by weight;

wherein the sugar comprises 10-30% of the matrix by weight; ~~and~~

wherein the composition does not comprise a synthetic polymer; and

wherein the pharmaceutical composition optionally comprises a pharmaceutically acceptable carrier.

2-6. (Canceled)

7. (Currently amended) The pharmaceutical composition of claim 1 wherein the pharmaceutical agent is a therapeutic agent.

8. (Currently amended) The pharmaceutical composition of claim 1 wherein the pharmaceutical agent is a local anesthetic.

9. (Currently amended) The pharmaceutical composition of claim 1 wherein the pharmaceutical agent is selected from the group consisting of procaine, lidocaine, dibucaine, tetracaine, bupivacaine, mepivacaine, and articaine.

10. (Currently amended) The pharmaceutical composition of claim 1 wherein the pharmaceutical agent is bupivacaine.

11. (Currently amended) The pharmaceutical composition of claim 1 wherein the pharmaceutical agent is an anticonvulsant.

12. (Currently amended) The pharmaceutical composition of claim 1 wherein the pharmaceutical agent is a vasodilator.

13. (Currently amended) The pharmaceutical composition of claim 1 or 101 wherein the pharmaceutical or diagnostic agent is a protein.

14. (Currently amended) The pharmaceutical composition of claim 1 or 101 wherein the pharmaceutical or diagnostic agent is a lipid.

15. (Currently amended) The pharmaceutical composition of claim 1 wherein the pharmaceutical agent is a glycosaminoglycan.

16. (Canceled)

17. (Currently amended) The pharmaceutical composition of claim 1 wherein the pharmaceutical agent is a prophylactic agent.

18. (Original) The pharmaceutical composition of claim 1 wherein the lipid is a naturally occurring lipid.

19. (Original) The pharmaceutical composition of claim 1 wherein the lipid is an emulsifier.

20. (Original) The pharmaceutical composition of claim 1 wherein the lipid is a surfactant.

21-22. (Canceled)

23. (Original) The pharmaceutical composition of claim 1 wherein the lipid has no charge.

24. (Original) The pharmaceutical composition of claim 1 wherein the lipid is a phosphatidylcholine.

25. (Original) The pharmaceutical composition of claim 1 wherein the lipid is dipalmitoylphosphatidylcholine (DPPC).

26. (Canceled)

27. (Original) The pharmaceutical composition of claim 1 wherein the lipid is a phospholipid.

28-29. (Canceled)

30. (Original) The pharmaceutical composition of claim 1 wherein the protein is an albumin.

31-36. (Canceled)

37. (Original) The pharmaceutical composition of claim 1 wherein the sugar is lactose.

38-46. (Canceled)

47. (Original) The pharmaceutical composition of claim 1 wherein the ratio of lipid to protein to sugar is approximately 3:1:1.

48-57. (Canceled)

58. (Original) The pharmaceutical composition of claim 1 wherein the microparticles are less than 10 micrometers in diameter.

59. (Original) The pharmaceutical composition of claim 1 wherein the microparticles are less than 5 micrometers in diameter.

60. (Original) The pharmaceutical composition of claim 1 wherein the microparticles are less than 1 micrometer in diameter.

61. (Original) The pharmaceutical composition of claim 1 wherein the microparticles are less than 500 nanometers in diameter.

62. (Currently amended) A method of preparing solid microparticles comprising ~~an~~ a pharmaceutical agent encapsulated in a lipid-protein-sugar matrix, the method comprising steps of:

providing ~~an~~ a pharmaceutical agent;

contacting the pharmaceutical agent with:

a lipid selected from the group consisting of phosphoglycerides; phosphatidylcholines; dipalmitoyl phosphatidylcholine (DPPC); dioleylphosphatidyl ethanolamine (DOPE); dioleyloxypropyltriethylammonium (DOTMA); dioleoylphosphatidylcholine; cholesterol; cholesterol ester; diacylglycerol; diacylglycerolsuccinate; diphosphatidyl glycerol (DPPG); hexanedecanol; fatty alcohols;

polyethylene glycol (PEG); polyoxyethylene-9-lauryl ether; a surface active fatty acid; palmitic acid; oleic acid; fatty acids; fatty acid amides; sorbitan trioleate (Span 85) glycocholate; surfactin; a poloxomer; a sorbitan fatty acid ester; sorbitan trioleate; lecithin; lysolecithin; phosphatidylserine; phosphatidylinositol; sphingomyelin; phosphatidylethanolamine (cephalin); cardiolipin; phosphatidic acid; cerebrosides; dicetylphosphate; dipalmitoylphosphatidylglycerol; stearylamine; dodecylamine; hexadecyl-amine; acetyl palmitate; glycerol ricinoleate; hexadecyl sterate; isopropyl myristate; tyloxapol; poly(ethylene glycol)5000-phosphatidylethanolamine; and phospholipids;

[[,]]a protein selected from the group consisting of an albumin, a gelatin, whole cell extracts, antibodies, enzymes, commercially available proteins, proteins purified from natural sources, recombinant proteins, and chemically synthesized proteins; and

[[, and]]a sugar selected from the group consisting of galactose, lactose, glucose, maltose, starches, cellulose and its derivatives, methyl cellulose, carboxymethyl cellulose, fructose, dextran and its derivatives, raffinose, mannitol, xylose, dextrins, glycosaminoglycans, sialic acid, chitosan, hyaluronic acid, and chondroitin sulfate; and

spray drying mixture of the pharmaceutical agent, the lipid, the protein, and the sugar to make solid microparticles,

wherein the microparticles are not liposomes;

wherein the pharmaceutical agent is encapsulated in the matrix;

wherein the microparticles are less than 50 micrometers in diameter;

wherein the lipid comprises 20-60% of the matrix by weight;

wherein the protein comprises 10-30% of the matrix by weight;

wherein the sugar comprises 10-30% of the matrix by weight; and

wherein the microparticles do not comprise a synthetic polymer.

63. (Currently amended) A method of administering ~~an~~ a pharmaceutical or diagnostic agent, the method comprising steps of:

providing a patient;

providing ~~solid microparticles~~ the solid microparticle of claim 86 or 104 or the pharmaceutical composition of claim 1 or 101 ~~an agent encapsulated in a lipid-protein-~~

~~sugar matrix, wherein the microparticles are not liposomes~~; and

administering the ~~microparticles~~ microparticle or pharmaceutical composition to the patient[[;]]

~~wherein the microparticles are not liposomes; wherein the agent is encapsulated in the matrix; wherein the microparticles are less than 50 micrometers in diameter; wherein the lipid comprises 20-60% of the matrix by weight; wherein the protein comprises 10-30% of the matrix by weight; wherein the sugar comprises 10-30% of the matrix by weight; and wherein the microparticles do not comprise a synthetic polymer~~.

64. (Currently amended) The method of claim 63 wherein the step of administering comprises injecting the ~~microparticles~~ microparticle or pharmaceutical composition into the patient.

65. (Currently amended) The method of claim 63 wherein the step of administering comprises placing the ~~microparticles~~ microparticle or pharmaceutical composition in a body cavity of the patient.

66-79. (Canceled)

80. (Previously presented) The pharmaceutical composition of claim 1 wherein the microparticles range from 3 microns to 5 microns in diameter.

81-83. (Canceled)

84. (Previously presented) The pharmaceutical composition of claim 1, wherein the microparticles are prepared by spray drying.

85. (Canceled)

86. (Currently amended) A ~~pharmaceutical composition comprising~~ solid microparticle~~microparticles~~, wherein the microparticle is ~~microparticles are~~ not a liposome~~liposomes~~, comprising:

(a) a matrix comprising:

a lipid selected from the group consisting of phosphoglycerides; phosphatidylcholines;

dipalmitoyl phosphatidylcholine (DPPC); dioleylphosphatidyl ethanolamine (DOPE); dioleyloxypropyltriethylammonium (DOTMA); dioleoylphosphatidylcholine; cholesterol; cholesterol ester; diacylglycerol; diacylglycerolsuccinate; diphosphatidyl glycerol (DPPG); hexanedecanol; fatty alcohols; polyethylene glycol (PEG); polyoxyethylene-9-lauryl ether; a surface active fatty acid; palmitic acid; oleic acid; fatty acids; fatty acid amides; sorbitan trioleate (Span 85) glycocholate; surfactin; a poloxomer; a sorbitan fatty acid ester; sorbitan trioleate; lecithin; lysolecithin; phosphatidylserine; phosphatidylinositol; sphingomyelin; phosphatidylethanolamine (cephalin); cardiolipin; phosphatidic acid; cerebrosides; dicetylphosphate; dipalmitoylphosphatidylglycerol; stearylamine; dodecylamine; hexadecyl-amine; acetyl palmitate; glycerol ricinoleate; hexadecyl sterate; isopropyl myristate; tyloxapol; poly(ethylene glycol)5000-phosphatidylethanolamine; and phospholipids;

(i) a sugar selected from the group consisting of galactose, lactose, glucose, maltose, starches, cellulose and its derivatives, methyl cellulose, carboxymethyl cellulose, fructose, dextran and its derivatives, raffinose, mannitol, xylose, dextrins, glycosaminoglycans, sialic acid, chitosan, hyaluronic acid, and chondroitin sulfate; and

(ii) a protein selected from the group consisting of an albumin, a gelatin, whole cell extracts, antibodies, enzymes, commercially available proteins, proteins purified from natural sources, recombinant proteins, and chemically synthesized proteins; and

(b) ~~an~~ a pharmaceutical agent, wherein the pharmaceutical agent is encapsulated in the matrix;

~~wherein the microparticles are not liposomes;~~ wherein the pharmaceutical agent is encapsulated in the matrix;

wherein the microparticle is~~microparticles are~~ less than 50 micrometers in diameter;

wherein the lipid comprises 20-60% of the matrix by weight;

wherein the protein comprises 10-30% of the matrix by weight;

wherein the sugar comprises 10-30% of the matrix by weight; and

wherein the microparticle~~composition~~ does not comprise a synthetic polymer.

87. (Currently amended) The solid microparticle~~pharmaceutical composition~~ of claim 86, wherein the lipid is dipalmitoyl phosphatidylcholine (DPPC).

88. (Currently amended) The solid microparticle~~pharmaceutical composition~~ of claim 86, wherein the protein is an albumin.

89. (Currently amended) The solid microparticle~~pharmaceutical composition~~ of claim 86, wherein the sugar is lactose.

90. (Currently amended) ~~A~~ The pharmaceutical composition of claim 1 or 101, wherein the lipid is ~~comprising solid microparticles, wherein the microparticles are not liposomes, comprising~~:

~~(a) a matrix comprising:~~

~~(i)~~ dipalmitoyl phosphatidylcholine (DPPC), the sugar is~~;~~

~~(ii)~~ lactose, and the protein is an albumin.~~; and~~

~~(iii) albumin; and~~

~~(b) an agent, wherein the agent is encapsulated in the matrix;~~

~~wherein the microparticles are not liposomes; wherein the agent is encapsulated in the matrix; wherein the microparticles are less than 50 micrometers in diameter; wherein the lipid comprises 20-60% of the matrix by weight; wherein the protein comprises 10-30% of the matrix by weight; wherein the sugar comprises 10-30% of the matrix by weight; and wherein the composition does not comprise a synthetic polymer.~~

91. (Currently amended) The pharmaceutical ~~compositions~~ composition of claim 1 or 101,~~any one of claims 1, 86, and 90~~, wherein the ratio of lipid to protein to sugar is approximately 3:1:1.

92-95. (Canceled)

96. (Currently amended) The pharmaceutical ~~compositions~~ composition of claim 1 or 101,~~any one of claims 1, 86, and 90~~, wherein the pharmaceutical or diagnostic agent is a small molecule.

97. (Currently amended) The pharmaceutical ~~compositions~~ composition of claim 1 or 101,~~any one of claims 1, 86, and 90~~, wherein the pharmaceutical or diagnostic agent is a protein.

98. (Currently amended) The pharmaceutical ~~compositions~~ composition of claim 1 or 101,~~any one of claims 1, 86, and 90~~, wherein the pharmaceutical or diagnostic agent is a polynucleotide.

99. (New) The pharmaceutical composition of claim 1, wherein the pharmaceutical agent is a drug.

100. (New) The pharmaceutical composition of claim 1, wherein the pharmaceutical agent is a vaccine.

101. (New) A pharmaceutical composition comprising solid microparticles comprising:

(a) a matrix of:

(i) a lipid selected from the group consisting of phosphoglycerides; phosphatidylcholines; dipalmitoyl phosphatidylcholine (DPPC); dioleylphosphatidyl ethanolamine (DOPE); dioleyloxypropyltriethylammonium (DOTMA); dioleoylphosphatidylcholine; cholesterol; cholesterol ester; diacylglycerol; diacylglycerolsuccinate; diphosphatidyl glycerol (DPPG); hexanedecanol; fatty alcohols; polyethylene glycol (PEG); polyoxyethylene-9-lauryl ether; a surface active fatty acid; palmitic acid; oleic acid; fatty acids; fatty acid amides; sorbitan trioleate (Span 85) glycocholate; surfactin; a poloxomer; a sorbitan fatty acid ester; sorbitan trioleate; lecithin; lysolecithin; phosphatidylserine; phosphatidylinositol; sphingomyelin; phosphatidylethanolamine (cephalin); cardiolipin; phosphatidic acid; cerebrosides; dicetylphosphate; dipalmitoylphosphatidylglycerol; stearylamine; dodecylamine; hexadecyl-amine; acetyl palmitate; glycerol ricinoleate; hexadecyl sterate; isopropyl myristate; tyloxapol; poly(ethylene glycol)5000-phosphatidylethanolamine; and phospholipids;

(ii) a sugar selected from the group consisting of galactose, lactose, glucose, maltose, starches, cellulose and its derivatives, methyl cellulose, carboxymethyl cellulose, fructose, dextran and its derivatives, raffinose, mannitol, xylose, dextrins, glycosaminoglycans, sialic acid, chitosan, hyaluronic acid, and chondroitin sulfate; and

(iii) a protein selected from the group consisting of an albumin, a gelatin, whole cell extracts, antibodies, enzymes, commercially available proteins, proteins

purified from natural sources, recombinant proteins, and chemically synthesized proteins; and

(b) at least one diagnostic agent; and

wherein the microparticles are not liposomes;

wherein the diagnostic agent is encapsulated in the matrix;

wherein the microparticles are less than 50 micrometers in diameter;

wherein the lipid comprises 20-60% of the matrix by weight;

wherein the protein comprises 10-30% of the matrix by weight;

wherein the sugar comprises 10-30% of the matrix by weight;

wherein the composition does not comprise a synthetic polymer; and

wherein the pharmaceutical composition optionally comprises a pharmaceutically acceptable carrier.

102. (New) The pharmaceutical composition of claim 101, wherein the diagnostic agent is an imaging agent.

103. (New) A method of preparing solid microparticles comprising a diagnostic agent encapsulated in a lipid-protein-sugar matrix, the method comprising steps of:

providing a diagnostic agent;

contacting the agent with:

a lipid selected from the group consisting of phosphoglycerides; phosphatidylcholines; dipalmitoyl phosphatidylcholine (DPPC); dioleylphosphatidyl ethanolamine (DOPE); dioleyloxypropyltriethylammonium (DOTMA); dioleoylphosphatidylcholine; cholesterol; cholesterol ester; diacylglycerol; diacylglycerolsuccinate; diphosphatidyl glycerol (DPPG); hexanedecanol; fatty alcohols; polyethylene glycol (PEG); polyoxyethylene-9-lauryl ether; a surface active fatty acid; palmitic acid; oleic acid; fatty acids; fatty acid amides; sorbitan trioleate (Span 85) glycocholate; surfactin; a poloxomer; a sorbitan fatty acid ester; sorbitan trioleate; lecithin; lysolecithin; phosphatidylserine; phosphatidylinositol; sphingomyelin; phosphatidylethanolamine (cephalin); cardiolipin; phosphatidic acid; cerebrosides; dicetylphosphate; dipalmitoylphosphatidylglycerol; stearylamine; dodecylamine; hexadecyl-amine; acetyl palmitate; glycerol ricinoleate; hexadecyl sterate; isopropyl

myristate; tyloxapol; poly(ethylene glycol)5000-phosphatidylethanolamine; and phospholipids;

a protein selected from the group consisting of an albumin, a gelatin, whole cell extracts, antibodies, enzymes, commercially available proteins, proteins purified from natural sources, recombinant proteins, and chemically synthesized proteins; and

a sugar selected from the group consisting of galactose, lactose, glucose, maltose, starches, cellulose and its derivatives, methyl cellulose, carboxymethyl cellulose, fructose, dextran and its derivatives, raffinose, mannitol, xylose, dextrins, glycosaminoglycans, sialic acid, chitosan, hyaluronic acid, and chondroitin sulfate; and

spray drying mixture of the diagnostic agent, the lipid, the protein, and the sugar to make solid microparticles,

wherein the microparticles are not liposomes;

wherein the diagnostic agent is encapsulated in the matrix;

wherein the microparticles are less than 50 micrometers in diameter;

wherein the lipid comprises 20-60% of the matrix by weight;

wherein the protein comprises 10-30% of the matrix by weight;

wherein the sugar comprises 10-30% of the matrix by weight; and

wherein the microparticles do not comprise a synthetic polymer.

104. (New) A solid microparticle, wherein the microparticle is not a liposome, comprising:

(a) a matrix comprising:

a lipid selected from the group consisting of phosphoglycerides; phosphatidylcholines; dipalmitoyl phosphatidylcholine (DPPC); dioleylphosphatidyl ethanolamine (DOPE); dioleyloxypropyltriethylammonium (DOTMA); dioleoylphosphatidylcholine; cholesterol; cholesterol ester; diacylglycerol; diacylglycerolsuccinate; diphosphatidyl glycerol (DPPG); hexanedecanol; fatty alcohols; polyethylene glycol (PEG); polyoxyethylene-9-lauryl ether; a surface active fatty acid; palmitic acid; oleic acid; fatty acids; fatty acid amides; sorbitan trioleate (Span 85) glycocholate; surfactin; a poloxomer; a sorbitan fatty acid ester; sorbitan trioleate; lecithin; lysolecithin; phosphatidylserine; phosphatidylinositol; sphingomyelin; phosphatidylethanolamine (cephalin); cardiolipin; phosphatidic acid; cerebrosides; dicetylphosphate;

dipalmitoylphosphatidylglycerol; stearylamine; dodecylamine; hexadecyl-amine; acetyl palmitate; glycerol ricinoleate; hexadecyl sterate; isopropyl myristate; tyloxapol; poly(ethylene glycol)5000-phosphatidylethanolamine; and phospholipids;

(i) a sugar selected from the group consisting of galactose, lactose, glucose, maltose, starches, cellulose and its derivatives, methyl cellulose, carboxymethyl cellulose, fructose, dextran and its derivatives, raffinose, mannitol, xylose, dextrins, glycosaminoglycans, sialic acid, chitosan, hyaluronic acid, and chondroitin sulfate; and

(ii) a protein selected from the group consisting of an albumin, a gelatin, whole cell extracts, antibodies, enzymes, commercially available proteins, proteins purified from natural sources, recombinant proteins, and chemically synthesized proteins; and

(b) a diagnostic agent, wherein the agent is encapsulated in the matrix;

wherein the agent is encapsulated in the matrix; wherein the microparticle is less than 50 micrometers in diameter;

wherein the lipid comprises 20-60% of the matrix by weight;

wherein the protein comprises 10-30% of the matrix by weight;

wherein the sugar comprises 10-30% of the matrix by weight; and

wherein the microparticle does not comprise a synthetic polymer.

105. (New) The solid microparticle of claim 104, wherein the lipid is dipalmitoyl phosphatidylcholine (DPPC).

106. (New) The solid microparticle of claim 104, wherein the protein is an albumin.

107. (New) The solid microparticle of claim 104, wherein the sugar is lactose.